UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte CHRISTOPHER T. BOYLE

Appeal 2007-3212
Application 09/716,146
Technology Center 3700

DECIDED: April 30, 2008

Before TONI R. SCHEINER, ERIC GRIMES, and LORA M. GREEN, *Administrative Patent Judges*.

SCHEINER, Administrative Patent Judge.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 from the final rejection of claims 16, 20, and 26-28, all the claims remaining in the application. The claims stand rejected as anticipated by the prior art. We have jurisdiction under 35 U.S.C. § 6(b).

We affirm.

STATEMENT OF THE CASE

"[T]he present invention relates to . . . an endoluminal stent . . . having cavitated regions with micropores that communicate a bioactive agent from the cavity to an area external the stent" (Spec. 1: 10-13).

Claims 16 and 20 are representative, and read as follows:

16. An endoluminal stent for delivering a bioactive agent to a situs in a body, comprising:

a plurality of structural elements forming a radially expandable cylindrical member, the plurality of structural elements having a wall thickness; wherein the structural elements are fabricated of a metal and comprising a base layer and a second layer covering the base layer, further comprising a void space intermediate the base and second layers and enclosed therebetween;

a plurality of pores passing through at least one of the base and second layers and communicating with the void space; and

at least one bioactive agent retained within the void space and elutable through the plurality of pores.

20. The endoluminal stent according to claim 16, further comprising a degradable plug residing within the plurality of pores to prohibit release of the at least one bioactive agent until the degradation of the degradable plug.

The claims stand rejected as follows:

I. Claims 16, 20, and 26-28 under 35 U.S.C. § 102(e) as anticipated by Brown (U.S. Patent 6,071,305, issued June 6, 2000).

II. Claims 16, 26, and 27 under 35 U.S.C. § 102(b) as anticipated by Monaco (International Patent Application WO 94/18906, published September 1, 1994).

III. Claims 16, 20, and 26-28 under 35 U.S.C. § 102(b) as anticipated by Yan (U.S. Patent 5,843,172, issued December 1, 1998).

IV. Claims 16, 26, and 27 under 35 U.S.C. § 102(b) as anticipated by Buirge (U.S. Patent 5,735,897, issued April 7, 1998).

FINDINGS OF FACT (FF)

1. Claim 16 on appeal is directed to a radially expandable endoluminal stent made up of a plurality of structural elements, where the structural elements "are fabricated of a metal and compris[e] a base layer and a second layer covering the base layer," i.e., both the base layer and the second layer are made of metal, with void space between the base and second layers, and pores in the base and/or second layer communicating with the void space. The void space contains a bioactive agent, which is elutable through the pores.

2. According to the Specification, "either forming wrought metal parts, such as capillary tubing, into the implantable device or forming the implantable devices by vacuum deposition techniques . . . [is] the preferred method of making the implantable structural elements" of the stents (Spec. 10: 18-20).

3. "Where an implantable device is to be formed from non-preexisting structural elements, vacuum deposition techniques may be employed to form the implantable structural body, such as sputtering, reactive ion etching, chemical vapor deposition, plasma vapor deposition, or the like" (Spec. 11: 2-5). Internal cavities and openings can be formed by depositing patterned sacrificial material "over a base layer of structural material, then depositing a second layer of structural material over the sacrificial material and the base layer" and removing the sacrificial material "to leave the internal cavities

and plurality of openings formed within the deposited bulk material" (Spec. 11: 10-13).

4. The stents are "preferably formed of a metal such as titanium . . . or stainless steel" (Spec. 8: 23-26).

5. "Because of their use as a structural scaffold and the requirement that stents be delivered using transcatheter approaches, stents necessarily are delivered in a reduced diametric state and are expanded or allowed to expand *in vivo* to an enlarged diametric state" (Spec. 5: 7-9).

Brown

6. Brown describes "a biologically active agent delivery stent" which is "expandable for supporting a body lumen" (Brown, col. 2, ll. 53-55).

7. Brown describes an expandable stent "formed from an elongated or tubular member . . . in the shape of a coil or helix" (Brown, col. 5, ll. 39-42), or "other configurations such as . . . expandable tube stents, roving wire stents, and wire mesh stents. Thus, the elongated member . . . may be the filaments or fibers which form a mesh stent" (Brown, col. 7, ll. 36-39).

8. The stents may be formed from "a biocompatible metal or alloy such as stainless steel, [or] titanium" (Brown, col. 7, ll. 15-16; col. 12, ll. 7-8).

9. For clarity, Brown's Figure 2 is reproduced immediately below:

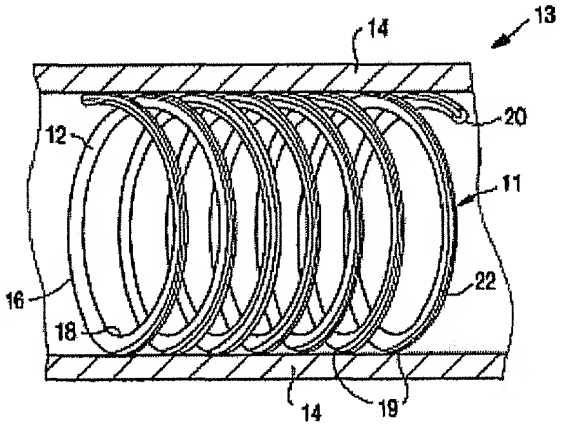

Figure 2 "is a cross sectional side view of a body lumen and a perspective view of a stent" (Brown, col. 3, ll. 62-63), "formed from an elongated or tubular member **12** . . . in the shape of a coil or helix" (Brown, col. 5, ll. 39-42).

10. "The tubular or elongated member **12** of the directional drug delivery stent **11** . . . is formed with an interior or cavity **20** . . . extending along the entire length of the elongated member" (Brown, col. 5, ll. 46-52), and "has a fluid opening or delivery means for directionally delivering a biologically active agent within the cavity or interior **20** . . . the fluid opening or delivery means may be a slit shaped opening **22** extending along the outer surface **16** of the stent which allows the active agent to be delivered from the cavity **20**" (Brown, col. 6, ll. 7-13). Alternatively, the fluid opening or delivery means may be "a series or plurality of holes, grooves, small indentations, . . . [or] intermittent recessions" (Brown, col. 6, ll. 15-16).

11. For clarity, Brown's Figure 5 is reproduced immediately below:

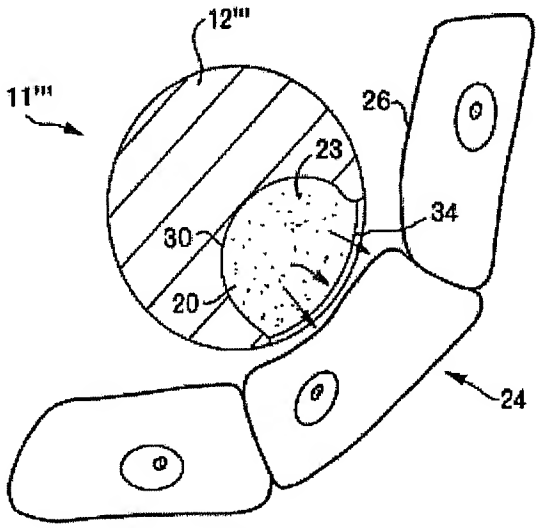

FIG. 5

Figure 5 "is an enlarged cross-sectional view of the elongated member [**12**] . . . positioned in a body lumen" (Brown, col. 4, ll. 8-11). Cavity **20** contains a biologically active agent **23**, and "membrane **34** . . . covers the slit shaped opening and allows the active agent to diffuse through the membrane to the desired predetermined location" (Brown, col. 9, ll. 13-15). Suitable membranes **34** include "poly-ethylene-vinyl acetate, polyethylene, polyesters, [etc.]" (Brown, col. 9, ll. 19-20).

12. For clarity, Brown's Figure 7 is reproduced immediately below:

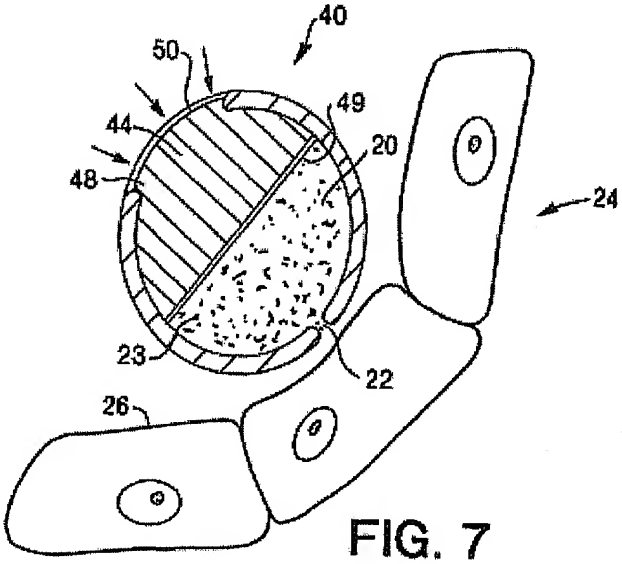

FIG. 7

Figure 7 "is an enlarged cross-sectional view of the elongated member [of] an osmotic directional delivery stent . . . positioned in a body lumen" (Brown, col. 4, ll. 16-18). "[T]he tubular member of the stent **40** is provided with a fluid inlet opening **48** which allows fluid from . . . the interior of the body lumen **24** to enter the osmotic agent **44** causing it to swell. The osmotic agent may be an osmagent, an osmopolymer, or a mixture of the two" (Brown, col. 9, ll. 43-48). The elongated member "also includes an optional separating member **49** between the osmotic agent **44** and the

biologically active agent **23** . . . [which] keeps the osmotic agent **44** separate from the biologically active agent **23** while also allowing the osmotic agent to swell. The separating member **49** may be . . . made of a flexible material that stretches as the osmotic agent imbibes fluid" (Brown, col. 10, ll. 43-51).

Monaco

13. Monaco describes an artificial organ that includes "a first housing having at least one interior and at least one exterior surface. The interior surface(s) define a chamber and the exterior and interior surfaces are in fluid communication with each other" (Monaco 3), and "the interior and exterior surfaces in closest facing relationship to each other are perforated" (*id.*). "A membrane is disposed within the chamber, at least a portion of the membrane being selectively permeable to bodily fluids. The membrane contains one or more cells . . . capable of producing a biological agent" (*id.*). "The selectively permeable membrane allows . . . body fluids to pass through . . . and permits a biological agent produced by the cells to pass through the membrane" as well (*id.*).

14. The first housing "can be comprised of, for example, stainless steel, [or] titanium" (Monaco 8), and can be "of sufficient thickness and of sufficient inflexibility to protect [the] membrane . . . from breakage" (*id.*).

15. Monaco's Figure 8 illustrates an artificial organ comprising "a pair of concentrically arranged [cylindrical] housings that are accessible to bodily fluids" (Monaco 20). Figure 8 is reproduced immediately below:

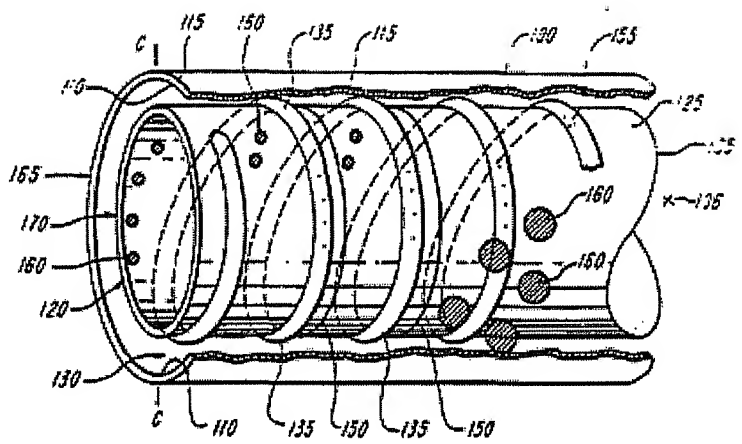

FIG. 8

Figure 8 "is a partial cut-away view of . . . [an] implantable artificial organ" (Monaco 6), in which "[a] substantially annular volume **130** is defined between the interior surface **110** of first housing **100** and exterior surface **125** of second housing **105**. Disposed within volume **130** is a selectively permeable membrane **135**" (Monaco 21), and "[c]ells **155** capable of releasing a biological agent, are disposed within the selectively permeable membrane **135**" (*id.*).

Yan

16. Yan describes an intra-vascular, radially-expandable stent that delivers a therapeutic agent to the site of implantation (Yan, col. 1, ll. 8-10).

17. The stent "is made of metal and has porous cavities in the metallic portion of the prosthesis so that . . . drugs can be loaded directly into the pores without substantially weakening the structural and mechanical characteristics of the prosthesis" (Yan, col. 1, ll. 63-67).

18. "[T]he porous cavities of the stent can be formed by sintering the stent material from metallic particles, filaments, fibers or other materials. The stent can be formed from a sintered wire . . . [or] from a sintered cylindrical

tube or sintered metal sheet which can be laser cut or chemical[ly] etched into an expandable stent structure" (Yan, col. 2, ll. 7-14).

19. Yan's Figure 12 illustrates a sheet that can be cut or etched into a stent configuration (Yan, col. 8, ll. 64-65). Figure 12 is reproduced below:

FIG. 12

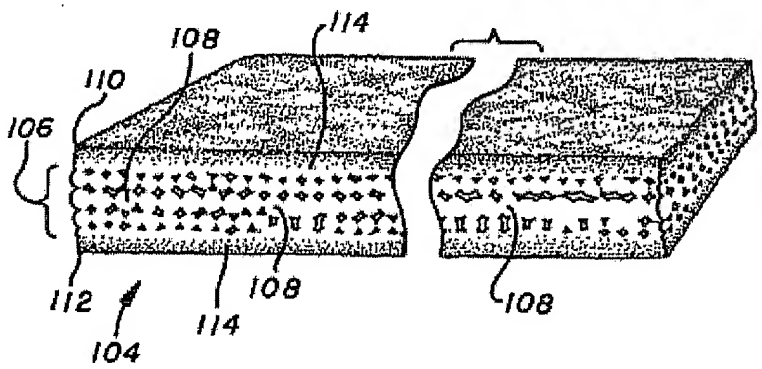

Figure 12 is a cross-sectional, partially cut away view of "a sintered sheet **104** of metal having a core **106** formed of large diameter particles **108** that form large pores. The core layer **106** is sandwiched between two layers **110** and **112** formed of smaller diameter particles **114** that form smaller diameter pores. Such a sheet is formed by orienting a middle or core layer **106** of large diameter particles along a plane. A top layer of smaller diameter particles is arranged in a plane parallel to and above the middle layer. A bottom layer of particles are arranged in a plane parallel to and below the middle layer. The three layers are pressed together and sintered into a single sheet" (Yan, col. 3, ll. 49-50, col. 8, ll. 53-64).

20. Yan's Figure 10 illustrates another sheet that can be formed into a stent by "loop[ing] [it] into a cylindrical formation" (Yan, col. 8, ll. 30-31). Figure 10 is reproduced immediately below:

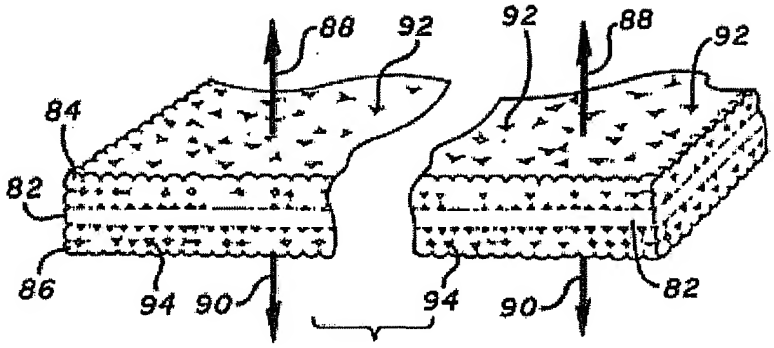

FIG. 10

Figure 10 is a cross-sectional, partially cut away view of a "sheet formed of sintered particles that are sintered to both sides **84** and **86** of a metal sheet **82**" (Yan, col. 8, ll.15-16). "[A] therapeutic agent loaded into the pores **92** on the top side of **84** the sheet permeates . . . outward from the solid core. A therapeutic agent loaded into the pores **94** on the bottom side **86** . . . permeates . . . [in the opposite] direction **90**" (Yan, col. 8, ll. 22-39).

21. Yan's stent can be coated with a bioabsorbable, polymeric "coating **100** [that] dissolves after implantation and . . . delays the time that a therapeutic agent is released into the vasculature of a patient. The thickness of the coating as well as the rate at which the coating is bioabsorbed determines the length of time . . . before a therapeutic agent is delivered from the pores of the stent" (Yan, col. 9, ll. 51-59).

Buirge

22. Buirge describes "an expandable stent-like structure which may be expanded in situ to fit the vessel in which it is being placed" (Buirge, col. 5, ll. 27-28), illustrated in Figures 1, 2, and 3, which are reproduced immediately below:

Fig. 1

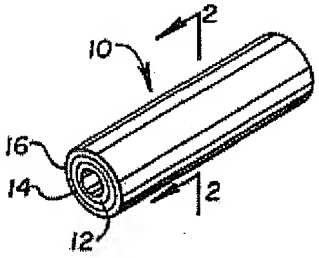

Fig. 2

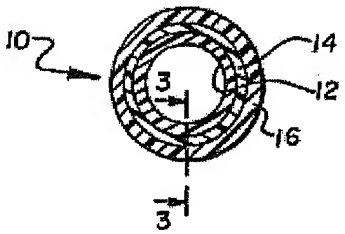

Fig. 3

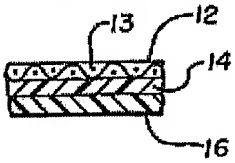

Figure 1 "is a schematic showing of the stent-like vascular prosthesis" (Buirge, col. 1, ll. 64-65); Figure 2 "is a cross-section view of the prosthesis of FIG. 1 taken along line 2—2" (*id.*, col. 1, ll. 66-67); Figure 3 "is a cross-section of the prosthesis of FIG.1 taken along line 3—3 of FIG. 2" (*id.*, col. 2, ll. 1-2).

23. Referring to Buirge's Figures 1, 2, and 3, layer **16** is the outer layer of the prosthesis; layer **14** is "the intermediate drug bearing layer"; and layer **12** is the "inner, bodily fluid contacting layer" (Buirge, col. 4, l. 66 to col. 5, l. 12).

24. Layers **12** and **16** of the stent-like prosthesis may be "[m]etals such as stainless steel and nitinol . . . in either a fixed diameter or expandable configuration" and "[f]urthermore, . . . may be in a mesh form, a screen form

or a filamentary form" (Buirge, col. 5, ll. 35-45). "[I]nner layer **12** may be rendered permeable by including openings therein of a size selected to provide any desired flow through rate and diffusion rate" (*id.*).

DISCUSSION

Brown

Claims 16, 20, and 26-28 stand rejected under 35 U.S.C. § 102(e) as anticipated by Brown. We will reverse this rejection.

The Examiner contends that Brown discloses several expandable endoluminal stents, specifically those shown in Figures 5, 7, 8, 10, and 12 "having the layers as claimed" (Ans. 5). For example, the Examiner finds that the embodiment shown in Brown's Figure 5 has a base layer **12** and a second layer **34**. As discussed above, Figure 5 shows the elongated member with a cavity **20** containing a biologically active agent **23**, covered by membrane **34**, which allows the active agent to diffuse out of the slit shaped opening (FF 11). Thus, elongated member **12** (characterized as a base layer by the Examiner) can be made of metal (FF 8), while membrane **34** (characterized as a second layer by the Examiner) is not (FF 11).

Similarly, the Examiner finds that the embodiment shown in Brown's Figure 7 has a base layer **40** and additional layers **44** and **49**, with a void layer **20** in between. As discussed above, according to Brown, **40** is the tubular member of a stent, while **44** is an osmotic agent that operates by imbibing fluid from the biological environment, swelling, and pressing on the flexible separating member **49**, compressing active agent **23** within cavity **20**, and ultimately pushing the active agent out of slit shaped opening **22** (FF 12). Tubular member **40** (characterized as a base layer by the

Examiner) may be made of metal (FF 8), but osmotic agent **44** and separating member **49** (characterized as additional layers by the Examiner) are not (FF 12).

Essentially, Appellant contends that Brown does not anticipate the claimed invention because claim 16, the only independent claim on appeal, "requires that the base and second layer be made of metal" (App. Br. 8).

The Examiner, on the other hand, contends that "the structural elements [of the claimed stent] are claimed to be fabricated of metal, [but] the 'layers' are not required . . . to be metal; that is the structural elements as a whole need only *comprise* metal and may include other materials as well" (Ans. 5).

We agree with Appellant that "use of the 'comprising' language modifies the base layer and the second layer, not [the] structural element or the metal" (App. Br. 7-8). "Thus, the claim may reasonably be interpreted as requiring at least a base layer and a second layer, . . . [and] could have other components, e.g., a third layer" as well (App. Br. 8), but the claim "requires that the base and second layer be made of metal" (App. Br. 8).

Brown does not describe a stent with a metal base layer and a second layer, also made of metal, wherein the base and second layers enclose a void space containing an active agent, and therefore, does not anticipate the claimed invention.

The rejection of claims 16, 20, and 26-28 under 35 U.S.C. § 102(e) as anticipated by Brown is reversed.

Monaco

Claims 16, 26, and 27 stand rejected under 35 U.S.C. § 102(b) as anticipated by Monaco. We will reverse this rejection.

Monaco describes an artificial organ comprising "a pair of [cylindrical] concentrically arranged housings that are accessible to bodily fluids" (Monaco 21, FF 15).

According to Appellant, endoluminal stents are "delivered using transcatheter approaches, so stents are delivered in a reduced diametric state and are expanded or allowed to expand in vivo to an enlarged diametric state" (Reply Br. 16). Appellant contends "there is no explicit or implicit limitation [sic, evidence?] that the Monaco artificial organ is radially expandable" (App. Br. 21). Thus, Appellant contends that Monaco does not meet "Claim 16's radially expandable limitation" (App. Br. 21).

The Examiner, on the other hand, contends that Monaco's cylindrical artificial organ is "radially expandable" because it is made of "titanium or stainless steel, two metals disclosed/admitted by *applicant* to be expandable" (Ans. 6).

We disagree with the Examiner's rationale and conclusion. The mere fact that both Monaco's device and Appellant's device can be made of the same material is not sufficient to establish that Monaco's device is radially expandable. Monaco's device comprises concentric cylindrical housings, with a tubular membrane wrapped around the inner cylindrical housing in a spiral fashion (Monaco Fig. 8; FF 15). The housings "can be comprised of, for example, stainless steel, [or] titanium" (Monaco 8; FF 14), "of sufficient thickness and of sufficient inflexibility to protect [the] membrane . . . from

breakage" (*id.*). The Examiner has not explained how Monaco's device can have a configuration that is inflexible enough to keep the membrane from breaking, and at the same time, be radially expandable.

The rejection of claims 16, 26, and 27 under 35 U.S.C. § 102(b) as anticipated by Monaco is reversed.

Yan

Claims 16, 20, and 26-28 stand rejected under 35 U.S.C. § 102(b) as anticipated by Yan. Appellant presents separate arguments with respect to claims 16 and 20. Claims 26-28 will stand or fall with claim 16, as provided by 37 C.F.R. § 41.37(c)(1)(vii) (2006).

We agree with the Examiner that Yan describes a radially expandable endoluminal stent (FF 16), with a sintered metal base layer (FF 17, 18, 19, 20), and second layer(s), also made of sintered metal (*id.*), with void spaces ("porous cavities") between the base layer and the second layer(s) (FF 18, 19, 20), pores passing through at least one of the base and second layers (FF 19, 20), and a bioactive ("therapeutic") agent loaded into the void spaces and elutable through the pores (FF 16, 17, 18). Moreover, we agree with the Examiner that Yan describes degradable plugs (dissolvable "coating **100**") in the pores that prohibit release of the bioactive agent until degradation of the plug (FF 21).

With respect to claim 16, Appellant argues that "Yan fails to disclose a base layer and second layer covering the base layer" (App. Br. 22), or "a void space intermediate between the layers and enclosed therebetween" (App. Br. 23). According to Appellant, "the outer surface region layers in [Yan's] figure 12 are not layers" (App. Br. 22) because they "are formed by

smaller diameter particles . . . result[ing] in the outer surface region having several thicknesses due to the varying diameter of the smaller particles" (*id.*). Similarly, Appellant argues that "[t]he middle region layer in figure 12 is . . . formed of large diameter particles **108**" (*id.*), thus, "[c]ore **106** would not be a single thickness, because at various points of the perimeter of core **106**, the large diameter particles [**108**] would form a thickness that varies with the circumference of the large diameter particles" (*id.*). In the Reply Brief, Appellant explains that he "has not argued a constant thickness, but rather a single thickness. A single thickness is required by a layer, as a plain and ordinary meaning" (Reply Br. 16).

These arguments are not persuasive. Yan describes the metal sheet shown in Figure 12 as having a core layer made from large diameter sintered particles oriented in a plane, which is sandwiched between two layers of smaller diameter sintered particles oriented in parallel planes on either side of the layer made from the large diameter particles (Yan, col. 8, ll. 53-64). Whether Appellant's contention is that Yan's "layers" are not layers because they are of variable thickness (i.e., they are bumpy, rather than perfectly uniform, flat, and smooth), or that they are not layers because they are not "single" thicknesses, the flaw in the contention is the same. Appellant has not pointed to anything in the Specification or the claims which requires layers of uniform thickness, or layers of a "single" thickness. In any case, once the particles are sintered, they are fused into a single thickness, even if they are several particles deep.

Finally, Yan clearly shows void spaces (small pores and large pores) in fluid communication between the layers, and retaining a bioactive agent

elutable from the top and bottom surfaces of the sheet (FF 19). Moreover, Yan's Figure 10 shows a sheet formed of particles sintered to both sides of a metal sheet, with therapeutic agents loaded into the pores on the top and bottom sides of the sheet, so that the agent in the top side pores elutes through the top particle layer to one side of the sheet, and the agent in the bottom side pores elutes through the bottom particle layer to the other side of the sheet (Yan, col. 8, ll. 15-39; FF 20).

With respect to claim 20, Appellant argues that Yan's dissolvable coating **100** is a "layer of a substance spread over a surface" rather than an "object used to fill a hole tightly" (App. Br. 23).

This argument is not persuasive. Yan's coating prevents release of the bioactive agent from the pores of the stent until after implantation, when the coating is dissolved (FF 21). Clearly, the coating temporarily plugs the pores on the surface of the stent. Appellant has not pointed to anything in the Specification or the claims which requires individual plugs in each pore, or which would exclude a coating layer that plugs multiple pores at the same time.

The rejection of claims 16, 20, and 26-28 under 35 U.S.C. § 102(b) as anticipated by Yan is affirmed.

Buirge

Claims 16, 26, and 27 stand rejected under 35 U.S.C. § 102(b) as anticipated by Buirge. The claims have not been argued separately, so claims 26 and 27 will stand or fall with claim 16, as provided by 37 C.F.R. § 41.37(c)(1)(vii) (2006).

We agree with the Examiner that Buirge describes a radially expandable endoluminal stent (FF 22), with a metal base layer (inner layer **12**) (FF 24), and a second layer (outer layer **16**), also made of metal (FF 24), with a bioactive agent-containing space ("intermediate drug bearing layer" **14**) between the base layer and the second layer (FF 23), and pores ("openings") passing through at least one of the base and second layers (FF 24), such that the bioactive agent is elutable through the pores (FF 24).

Appellant argues that Buirge's "intermediate layer **14** is the drug or therapeutic containing matrix and may be comprised of various aqueous solutions" and "would not be a void, i.e. empty and containing no matter" (App. Br. 24). Therefore, Appellant argues, Buirge does not describe an "intermediate void space enclosed [between]" a base layer and a second layer (App. Br. 25).

This argument is not persuasive. The "void" required by present claim 16 is not "empty and containing no matter" either. Rather the claim requires a void between the base and second layers containing "at least one bioactive agent" (i.e., a bioactive agent-containing reservoir). Buirge's intermediate layer **14** is a "void" in the same sense, i.e., layer **14** is a reservoir containing/retaining a bioactive reagent between inner layer **12** and outer layer **16**.

The rejection of claims 16, 26, and 27 under 35 U.S.C. § 102(b) as anticipated by Buirge is affirmed.

SUMMARY

The rejections of the claims as anticipated by Brown and Monaco are reversed. The rejections of the claims as anticipated by Yan and Buirge are affirmed.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1)(iv)(2006).

AFFIRMED

dm

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